NFPA
The Food Safety People

NATIONAL FOOD PROCESSORS ASSOCIATION

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VIA EMAIL

Dockets Management Branch
Mail Code HFA-305
Food and Drug Administration
Rm 1061
5630 Fishers Lane
Rockville, MD 20852
http://www.fda.gov/dockets/ecomments

RE: Docket No. 02N-0278; RIN 0910-AC41
Comments on Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

Dear Sir or Madam:

The National Food Processors Association (NFPA) appreciates the opportunity to submit comments on the interim final rules intended to comply with provisions of The Public Health Security and Bioterrorism Preparedness and Response Act (Act), and published in the Federal Register on October 10, 2003 (68 FR 58974). On August 30, 2002, NFPA submitted comments urging a seamless integration with existing systems to minimize unnecessary, multiple or redundant notifications. On March 5, 2003, NFPA submitted comments to the Office of Management and Budget (OMB) specifically related to the information collection aspects of the proposed rule. On April 3, 2003, NFPA identified burdensome and ineffective requirements of FDA's proposed rules and suggested reasonable alternative solutions to reduce the impact on trade in food products. Today's comment commends FDA for making significant positive changes to the proposed rules and highlights some remaining concerns and possible solutions to ease transition into the new regulations. NFPA welcomes the opportunity to work with FDA to resolve those concerns prior to finalizing the interim rules.

NFPA is the voice of the $500 billion food processing industry on scientific and public policy issues involving food safety, food security, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers, its scientists, and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, education, communications and crisis management support for the Association's U.S. and international members. NFPA members produce processed and packaged fruit, vegetable, and grain products, meat, poultry, and seafood products, snacks, drinks and juices, or provide supplies and services to food manufacturers. NFPA

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members import ingredients for further processing and are affected by the rulemaking that has been mandated under the Act.

General Comments

NFPA generally believes that the interim final rules have come a long way towards addressing the many issues raised in previous comments. NFPA strongly supports the ongoing dialogue with the Bureau of Customs and Border Protection (CBP) that has resulted in better integration of agency reporting requirements and will allow approximately 90 percent of food importers to submit prior notice information through the Automated Broker Interface (ABI). In addition, the interim final rules reduced filing times and based those times on mode of transportation as recommended in NFPA's previous comments and as consistent with statutory language. NFPA also appreciates the clarification provided in terms of definitions and terms applicable to prior notice submissions. In particular, NFPA believes that the discretionary enforcement period is appropriate and has already proven to be necessary to allow a smooth transition, without disrupting trade as these significant new rules become implemented. NFPA appreciates the opportunity provided for additional stakeholder comment on interim final rules and/or compliance guidance prior to publishing final rules. NFPA is optimistic that, after some months of experience under the interim rules, the majority of the remaining concerns can be identified and addressed effectively and efficiently.

Saying that, NFPA notes that there remain some key concerns that, without prompt resolution, will have significant adverse impacts on U.S. food companies. These issues relate specifically to: (1) harmonization of timelines with CBP; (2) requiring prior notice information for samples intended for research and development and consumer to consumer shipments; and (3) defining benefits for low-risk shippers. In addition, these comments highlight provisions requiring better clarification and problematic data elements.

Because the FDA Prior Notice Interface System became accessible only December 12, 2003 and the comparable Automated Broker Interface (ABI) software only days earlier, sufficient "experience" does not yet exist to make meaningful or substantive comments about the systems, timeframes, data elements, implementation process or operational impact. Consequently, NFPA welcomes the opportunity to file comments on those issues when FDA reopens the comment period for thirty days in March.

Harmonization with Customs

In previous comments, NFPA stressed the critical importance of a seamless integration with the notification requirements of CBP. The interim rules have achieved much to accommodate a single window to government for notification of over 90 percent of all imported food products. However, the time frames for notification to FDA under the interim rules for prior notice and to CBP under final rules for advance manifest

information are not yet completely harmonized. The CBP rules, under the Trade Act of 2002, require notice from rail carriers two hours prior to entry; FDA requires four hours. CBP requires one hour notice prior to entry by truck or 30 minutes by FAST carriers; FDA requires 2 hours with no recognized benefit for low-risk shippers. NFPA believes that rail carriers and truckers are likely to submit information concurrently to meet the requirements of both FDA and CBP regulations and, consequently, urges FDA to reduce time frames to harmonize with those under the Trade Act. Harmonization of these requirements will avoid unnecessary confusion and costly duplication of data reporting.

Research Samples

NFPA strongly urges FDA to reconsider exemptions from prior notice requirements for products that are not destined for commercial or retail consumption within the United States, particularly for products intended for research and development. The interim final rules indicate that exemption applies only to samples "that are in such early stages of research and development that they cannot yet be considered food." NFPA asserts that the requirement of prior notice for samples is unnecessarily burdensome and, unless modified, will discourage (even prohibit) U.S. companies from conducting legitimate food product research within this country. The requirements will force domestic firms to move research and development operations to Canada or other foreign countries. Consider the following:

- Common business practice includes purchasing samples from retail stores in foreign countries and bringing them to the U.S. for analysis and research. U.S. food companies may be interested in duplicating successful foreign products or evaluating their specific attributes. In such a case, prior notice would be required including **mandatory registration information on the manufacturer of the product.** The manufacturer of those foreign samples may not do business in the U.S. and, consequently, FDA registration is not required.

  Even if the company is registered with FDA, **the foreign company has no obligation to share registration information with the retail outlet or his U.S. competitor.**

- A U.S. representative may obtain several hundred small retail samples internationally, and commingle them in a container for shipping to a U.S. research and development facility. Each of these products may share an identical FDA product code but are from a variety of manufacturers. In this case, the shipper would **not have access to registration numbers but would also be unnecessarily burdened by the necessity of filing hundreds of prior notices** for a single small R & D shipment of samples.

- Multi-national companies ship R & D samples between corporate and facility locations at various steps in the research process. Corporate facilities in foreign countries not engaged in retail sales (or engaged in U.S. sales) would not be obligated

to register with FDA except for the specific purpose of providing samples to their U.S. facilities.

Corporate to corporate shipments or sample shipments to research facilities that are not intended for public consumption are highly unlikely to pose a security risk. NFPA refers FDA to federal meat inspection regulations (9 CFR, Part 327.16) and poultry inspection regulations (9 CFR Part 381.207) that provide limited inspection exemption for meat and poultry products that are intended for personal consumption or for laboratory analysis but not for retail distribution. FSIS requires the shipment to contain a certifying statement describing the intended use. FDA has already provided a limited exemption for homemade products or products for personal consumption but responds that exemptions cannot be provided for *de minimis* shipments because the "value is not necessarily a good indication of the article" and that low-volume or low-value products could have a broad health impact. NFPA does not disagree with FDA's response but asserts that the risk is minimized simply because samples are not intended for public consumption or distribution and because the responsible party, should any problem arise, can be easily identified (e.g. the research facility indicated as an importer on the certifying statement.)

NFPA refers to the interim final rules and FDA's discussion of the definition of food. FDA concludes that it is appropriate to exclude food contact materials and notes, "In addition, it is consistent with the "food for consumption" language in section 415(a) (1) (FD&C Act) of the registration provision. FDA notes, in discussing facility registration, that "Congress apparently intended to limit the term 'food' to something less than the broad definition..." An exemption from the requirements of prior notice for research samples that are not consumed publicly would, therefore, be appropriate.

NFPA recommends that:

- FDA expand the exemption for samples "that are in such early stages of research and development that they cannot yet be considered food" to include all samples that are not intended for retail consumption;
- FDA provide a limited exemption for corporate to corporate samples;
- FDA determine that facility registration and/or shipper registration numbers are not required for submission of prior notice for samples intended for research and development.
- FDA allow a single prior notice without registration numbers for commingled shipments of many small items falling under the same or similar FDA product codes if such products are intended for research and development.
- FDA expand the exemption for food carried in for personal use to include **all** food products carried in personal baggage; or to allow declaration of entry to be made through existing general CBP entry declaration procedures.

These exemptions may require a simple technology adjustment to identify a specific shipment category: samples for research and development.

Consumer to Consumer Shipments

Similar to samples for research and development, exemptions from prior notice must be provided for consumer- to- consumer shipments. For example, a consumer purchases food products at retail in a foreign country to send to friends, business colleagues or family within the U.S. Corporate gifts are also sent from foreign companies to clients within the U.S. Manufacturers of these products cannot control the final destination of their products and may have no other reason to register with FDA. Even if registered, retailers, consumers and shippers would have no access to the registration information.

Food companies report that they have already received requests from consumers for registration information for exactly this purpose. NFPA recommends:

- FDA should expand that exemption already provided for homemade food products sent as gifts or food items carried in for "personal consumption" to include all gifts (sent by any mode of transportation) intended for personal use.
- FDA should not require registration information on any consumer-to-consumer shipments.

Failure to provide for such an exemption threatens to overload agency prior notice systems and to compromise proprietary information regarding company registrations.

Recognized Benefits for Low-Risk Shippers

In previous comments, NFPA urged FDA to rely on CBP's existing targeting programs and to recognize security systems already in place that identify low-risk shippers. Many food companies are participating in Customs Trade Partnership Against Terrorism (CTPAT) and are using the Free and Secure Trade (FAST) carrier transport across the Northern borders. Time frames in final rules for cargo information under the Trade Act allow reduced reporting times for FAST carriers (30 minutes for FAST truckers; one hour for all others). As FDA works towards harmonizing time frames with CBP, NFPA urges the Agency to provide the same recognition for "low-risk" shippers as CBP. Recognized benefits for partnering with the trade community will advance U.S. security goals while allowing better targeting of agency enforcement resources.

Problematic Data Elements

The interim final rules have eliminated some unnecessary data elements and have reduced data redundancy between FDA and CBP. In addition, FDA has added important flexibility to provide for estimates of quantities and arrival times and "anticipated" ports of entry. These provisions, coupled with reduced time frames, will significantly reduce the need for amendments and the impact upon trade and business operations.

Yet, FDA is still requiring a significant amount of data for prior notice submission and data entry is very time consuming which gives rise to the following specific problems:

- **FDA Product Codes.** FDA's product code builder provides good instruction to assist food companies to identify their products for purposes of prior notice. In some cases, however, there is no single code or no exact code to describe a product; FDA's codes may be too specific or open to interpretation. Therefore, **FDA should allow submitters some flexibility in "coding" products. Products should not be refused for minor "coding" discrepancies.**
- **Trip Numbers.** Trip numbers cannot be assigned until a truck has been loaded and is ready for departure. For food companies, this means that prior notice cannot be provided until departure, requiring carriers to hold after loading to meet two hour time frames. The trip number is not necessary to identify the shipment. **FDA should eliminate the mandatory requirement for trip number.**
- **Estimated Arrival Times.** Maintaining the flexibility, as provided by the interim final rules, to provide **anticipated port arrival information for date and time of arrival, and point of crossing is critical to minimize trade disruption.** Times of arrival and entry locations will change and importers need the flexibility to accommodate these unanticipated changes without refilling entry information.

  The CBP/FDA Memorandum of Understanding provides for CBP to examine and hold shipments at ports where FDA may not be available. Considering the number of changes the industry anticipates, one questions the value in providing anticipated "times" at the time of filing. As FDA and CBP move forward to harmonize reporting time frames, NFPA suggests that the Agencies explore alternative ways to "update" arrival information to minimize the reporting burden for industry and confusion at port for agency officials. "Anticipated" arrival information can be provided to meet the requirements of prior notice, but these data elements require the carrier to be included in the information loop. If "time" and "crossing" information was not required at the time of filing prior notice but could be (as an option) communicated directly between carrier and CBP at the border approach (or in compliance with the advance manifest requirements), prior notice may be simplified for some companies with improved timing accuracy to assist border personnel.

Clarification Required

NFPA commends FDA for the definitions and clarification provided through the interim final rules responsive to many of our questions. Food companies continue to have questions on the following issues:

- **Dual use products**. The interim final rules explain: "FDA will consider an article one that will be used for food if any of the persons involved in importing or offering the product for import...reasonably believes that the substance is reasonably expected to be directed to food." NFPA notes that FDA regulated products will be "flagged"

for prior notice by the harmonized tariff codes. Irrespective of the intended final use of the product, it seems conceivable that if prior notice was not provided, it could be flagged and held while FDA determined the intended use. The hold could detain other products without a reasonable justification. FDA should work with Customs to develop a procedure to identify common "dual" use products to avoid unfair targeting and resulting disruption in trade.

- **Commodity products**. FDA indicates that prior notice will be required "even if the food is not yet in the form..." for final food use. FDA uses the example of green coffee. FDA should clarify applicability of these rules to commodity type products that may have a food use such as seeds or grains.
- **Prior notice confirmations.** FDA clearly indicates that the confirmations will be returned to the transmitter/submitter through either the ABI or Prior Notice Interface System (PNIS). FDA indicates that the confirmation number must accompany shipments by international mail or any notifications filed through the PNIS. FDA recommends that the confirmation number be provided to the carrier. Information shared during FDA/CBP briefings on the Northern border indicated that drivers without PN numbers would be redirected to the border broker for processing as an IE, and the shipment returned to the shipper. This is inconsistent with the interim rules and is not acceptable. PN confirmation numbers are accessible to border brokers and should not be required to be displayed by the carrier. FDA should clarify this issue.

  FDA should also indicate an appropriate time frame to wait for PN confirmation before assuming the system in down and/or that resubmission is required.

- **Clarify ports**. If goods move for immediate export (IE) out of the same port they are not subject to prior notice, but when they move on a transshipment and export (T & E), a prior notice is required. For example, a shipment may move from Los Angeles harbor to Los Angeles airport, which have two separate port codes. CBP would consider this an IE entry. Will FDA's prior notice requirements be consistent with those of CBP for IE entries or is this considered a T & E entry requiring prior notice?

- **Information on held shipments.** NFPA member companies continue to question procedures for held shipments. Specifically, companies are concerned that notice of noncompliance on held shipments would be provided to carriers and not to the consignee or importer. Carriers may not be involved in prior notice requirements and, in some cases, have minimal vested interest in an off loaded container. NFPA urges FDA to reconsider this issue following some months of experience in order to facilitate efficient correction of any notification failures and to clear shipments to and from storage.

  FDA should also clarify procedures for resubmission when a shipment is refused for other than prior notice failure. Submission of a "re-file" through the FDA PNIS that was originally submitted through ABI introduces new communication loops through the carriers.

- **Conditional release**. FDA should also clarify expectations at the border regarding "may proceed" decisions. The interim rules indicate "the system will transmit a message back through OASIS to ABI/ACS interface for CBO that the article of food may be conditionally released." FDA also indicates that staff operating "24 hours a day, seven days a week" will review at the port of arrival or closest examination site. This leads the industry to believe that decisions were to be made a port of entry; yet companies report that since December 12, 2003, conditional release" messages have not consistently been received at entry. FDA should clarify when this message should be received and the implications for companies that enter the U.S. within the "release."

Summary

NFPA is committed to the important goal of protecting the nation's food supply against intentional contamination and welcomes the opportunity to work with FDA as final rules are developed that respond to the key mandates of the Bioterrorism Act. NFPA applauds FDA for building a cooperative relationship with CBP in order to achieve an integrated notification system that minimizes the disruption to trade and business operations.

However, these new rules have imposed significant new operational burdens on food companies, brokers, shippers and other parties. FDA's discretionary enforcement period incorporating broad educational outreach is necessary and appropriate. NFPA encourages continued dialogue with CBP in order to fully harmonize notification systems and better clarify the outstanding issues identified in this comment.

Most important, NFPA strongly encourages FDA to take into consideration the operational realities of research and development. Product research and development is critical to business success and to achieve the common goal of safe high quality foods. Innovative food products also build U.S. exports. Without a satisfactory accommodation for imported research samples, this critical component of the domestic food industry will be largely forced "offshore" or potentially out of business.

Thank you for your consideration of these comments.

Sincerely,

John R. Cady

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